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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,015	01/14/2004	Axel Riedel	01-1443	3296

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,015	RIEDEL ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 8-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *21Aug08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 8-35 are presented for examination.

Applicant's Amendment and Information Disclosure Statement (IDS) filed August 21, 2008 have each been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08a (one page total), the Examiner has considered the cited references.

Claims 1 and 8-35 remain pending and under examination. Claims 1, 18-20, 24-26 and 29 are amended.

Applicant's arguments, filed August 21, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 8-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of asthma, bronchitis, interstitial lung disease, insulin resistance, prediabetes, type 2 diabetes mellitus, metabolic syndrome, hypertension combined with hyperlipidemia or hypertension combined with atherosclerosis comprising the administration of telmisartan (or a salt thereof) with simvastatin (or a salt thereof), does not reasonably provide enablement for the prevention of the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

For the purposes of consideration under 35 U.S.C. 112, first paragraph, the instant rejection focuses on the particular condition of metabolic syndrome, as recited in present claim 1. However, the reasons stated here concerning the burden of enabling the prevention of the prediabetic condition of metabolic syndrome apply also to myriad of other conditions encompassed by the present claims, but for the obvious difference in the type of disorder.

The presently claimed invention is directed to a method for the prevention or treatment of asthma, bronchitis, interstitial lung disease, insulin resistance, prediabetes, type 2 diabetes mellitus, metabolic syndrome or hypertension combination with hyperlipidemia or atherosclerosis in a mammal comprising administering a pharmaceutical composition comprising telmisartan or one of the salts thereof and simvastatin (see, e.g., claim 1).

In particular, one skilled in the art could not practice the presently claimed subject matter without undue experimentation because the artisan would not accept on its face that the prevention of metabolic syndrome, by administering a pharmaceutical composition of telmisartan or a salt thereof with simvastatin

(or a salt thereof), could actually be achieved. Based upon the state of the art, as discussed below, the artisan would have only accepted that the treatment of such a condition could be achieved with this specific combination of agents.

As set forth in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains the teachings of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112, *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support*; assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling." (emphasis added)

The present claims circumscribe a method for preventing metabolic syndrome by administering a pharmaceutical composition of telmisartan (or a salt thereof) with simvastatin (or a salt thereof). That is, in order to be enabled to practice the present invention, the skilled artisan would have to accept that by administering this combination of telmisartan and simvastatin, patients (both those that exhibit pre-disposing factors and/or conditions as well as those that do not overtly exhibit pre-disposing factors and/or conditions) would be protected against developing such a disorder. In other words, the skilled artisan would have understood the term "prevention" to mean that the claimed therapy was capable of impeding the development of such a condition such that it would be "prevented", i.e., reasonably expected not to occur, in such a population treated via the instantly claimed therapy. Because such preventive success is not reasonably possible with most diseases or disorders, especially a condition as complex and poorly understood as metabolic syndrome, the specification, which lacks any direction or guidance as to how prevention of metabolic syndrome could actually be achieved, is viewed as lacking an

enabling disclosure of the entire scope of the claimed invention.

Regarding the prevention of metabolic syndrome, the objective truth that such a condition may be prevented is doubted because the art expressly recognizes the complex nature and poor understanding of this syndrome and the predisposing factors that characterize this condition.

In this regard, Grundy ("Metabolic Complications of Obesity", Endocrine, 2000) is cited. Applicant's attention is drawn particularly to the abstract, which states, "The rising prevalence of obesity is accompanied by an increasing number of patients with the metabolic complications of obesity. The major complications come under the heading of the metabolic syndrome. This syndrome is characterized by plasma lipid disorders (atherogenic dyslipidemia), raised blood pressure, elevated plasma glucose, and a prothrombotic state. The clinical consequences of the metabolic syndrome are coronary heart disease and stroke, type 2 diabetes and its complications, fatty liver, cholesterol gallstones, and possible some forms of cancer. At the heart of the metabolic syndrome is insulin resistance…Obesity is the predominant factor leading to insulin resistance, although other factors play a role. The mechanistic link between insulin resistance and the metabolic syndrome is complex. The relationship is modulated by yet other factors, such as physical activity, body fat distribution, hormones, and a person's genetic polymorphic architecture. A better understanding of the molecular basis of this relationship is needed…In addition, understanding at the clinical level will lead to improved management of these complications."

Given that the art expressly acknowledges that the condition of metabolic syndrome and insulin resistance (the primary condition that characterizes metabolic syndrome and results in impaired glucose utilization) as being complex, the skilled artisan would have recognized that the state of the art with regard to metabolic syndrome is not well defined, and is, therefore, unpredictable, such that one of ordinary skill in the art would not accept on its face Applicant's statement that metabolic syndrome could be prevented because the pathophysiology of such a condition is not particularly well characterized. In

light of such, the artisan would have required sufficient direction as to how the administration of the presently claimed combination of active agents could actually prevent the development of metabolic syndrome and the patient population in need of prevention could have been readily identified without requiring an undue level of experimentation such that the artisan would have been imbued with at least a reasonable expectation of success. Such success would not have been reasonably expected give that prevention is an outcome not reasonably expected by one of ordinary skill in the art and, further, Applicant has failed to provide any guidance as to how such a population of patients would be identified such that the presently claimed combination of agents could actually be used for achieving the objective of prevention. Absent this disclosure, the present specification fails to enable the full scope of this invention as it relates to the objective of prevention and, thus, fails to rebut the presumption of unpredictability in the art with regard to this same objective.

Furthermore, given the breadth of conditions characterizing metabolic syndrome (i.e., plasma lipid disorders (atherogenic dyslipidemia), raised blood pressure, elevated plasma glucose, and a prothrombotic state), prevention or prophylaxis against metabolic syndrome would necessarily involve preventing each one or more of the conditions known to be associated with such a syndrome. Such a situation would require the skilled artisan to determine whether the active agents of the present claims are effective in preventing any one or more of these conditions and such a process would amount to undue experimentation, given the breadth and disparate nature of each of these conditions and the poor clinical understanding of metabolic syndrome in general.

Moreover, despite the fact that the art recognizes particular pathophysiological manifestations that contribute to the development of metabolic syndrome (see Grundy, citation *supra*), the fact that a patient may exhibit any one or more of such symptomatic complications does not necessarily mean that the patient is predisposed to developing metabolic syndrome. It is the occurrence and interaction of multiple physiological symptoms, as well as other physiologic factors, such as obesity, genetic conditions

and/or predispositions, body fat distribution, etc., that contribute to the development of the condition. Accordingly, the circumstances of each individual patient must be carefully considered when determining patients in need of metabolic syndrome prevention. In other words, the variability among patients precludes a common, art-accepted protocol for metabolic syndrome prevention in all patients, given that each patient has risk factors or circumstances unique to that individual, which must be taken into consideration when determining the most effective approach to prevention of metabolic syndrome.

It is in this regard that Applicant is directed to the MPEP at §2164.08. All questions of enablement are evaluated against the claimed subject matter. Concerning the breadth of a claim relevant to enablement, the only relevant concern is whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of enablement involves the determination of how broad the claim is with respect to the disclosure and the determination of whether one skilled in the art is enabled to use the *entire scope* of the claimed invention without undue experimentation.

Applicant's instant specification conspicuously lacks any disclosure or teaching of manner and process of using the presently claimed combination of telmisartan and simvastatin for achieving the objective of prevention of metabolic syndrome. Nowhere does the specification disclose how those patients in need of prevention of metabolic syndrome could be identified, what criteria would be used to determine such patients and how they would be treated using the presently claimed combination of agents such that the skilled artisan would have been imbued with at least a reasonable expectation of success in determining such patients without the burden of an undue level of experimentation. Due to the unpredictable nature of the pathophysiological manifestations of metabolic syndrome and the poor clinical understanding of this condition in the art, as well as the absence of any guidance or direction as to how the skilled artisan would go about identifying patients in need of prevention, the instant disclosure is

viewed as lacking enablement for this aspect of the present invention.

In light of these reasons, it is clear that the present specification fails to provide adequate guidance as to how one skilled in the art would accomplish the objective of preventing metabolic syndrome, given what is disclosed in the present specification. Given the highly unpredictable state of the art and, furthermore, given that Applicant has failed to provide adequate guidance or direction as to how to practice the full scope of the presently claimed invention without undue experimentation, the specification lacks any basis for claiming the prevention of metabolic syndrome without obligating the skilled artisan to perform an undue level of experimentation in order to determine how such an aspect of the invention would actually be practiced. For these reasons, Applicant has failed to obviate the presumption of unpredictability in the art.

The basis for the present rejection is not simply that experimentation would be required, since it is clear from the state of the prior art and Applicant's disclosure and remarks that experimentation in this particular art is not at all uncommon, but that the experimentation required in order to practice this aspect of the invention would be *undue*. Please reference *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, "The test of enablement is not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue*." (emphasis added)

In view of the discussion of each of the preceding seven factors, the level of skill in the art is high and is at least that of a medical doctor with several years of experience in the art.

As the cited art and discussion of the above factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that prevention of the claimed disorders could be achieved using telmisartan or a salt thereof in combination with simvastatin or a salt thereof. In order to actually achieve such a result, it is clear from the discussion above that the skilled artisan could not rely upon Applicant's disclosure as required by 35 U.S.C. 112, first paragraph, and would have no alternative recourse but the impermissible burden of undue

experimentation in order to practice the full scope of the embodiments of the presently claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 8-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over De Gasparo et al. (WO 01/76573; 2001) in light of Robl et al. (U.S. Patent Application Publication No. 2002/001334; January 31, 2002), cited to show a fact, in view of Cecil's Textbook Of Medicine (2000), Harlan et al. (U.S. Patent Application Publication No. 2001/0006656; July 2001) and Bohm et al. (WO 02/15891; February 2002), each already of record, for the reasons of record set forth at p.19-23 of the previous Office Action dated February 22, 2008, of which said reasons are herein incorporated by reference.

Applicant again traverses the instant rejection, stating that De Gasparo et al. fail to disclose the specific combination of telmisartan and simvastatin anywhere in the reference. Applicant further alleges that De Gasparo et al. lists a number of commercially available sartans, including telmisartan, but fails to

disclose this specific compound "as a selected compound in the context of a specific combination, much less with simvastatin" (p.18, Remarks). In fact, Applicant submits that the only sartan mentioned in the reference in the context of a specific combination is valsartan, which Applicant alleges constitutes a teaching away from the use of telmisartan. Applicant makes the same allegations with regard to simvastatin, stating that the compound is not mentioned in combination with telmisartan. Applicant submits that the secondary references, i.e., Robl et al., Cecil's Textbook of Medicine, Harlan et al. or Bohm et al., do not provide motivation, reasonable expectation of success, or a teaching or suggestion of all of the claim limitations of the invention. Still further, Applicant submits that neither the primary nor the secondary references teach or suggest telmisartan increases the expression of genes regulated by the PPAR-gamma receptor, which is the reason that telmisartan is a preferred combination partner for simvastatin in the treatment of, e.g., diabetes.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

In response, Applicant's attention is once again directed to p.17-18 of the Office Action dated March 30, 2006, which sets forth the teachings of De Gasparo et al. insofar as the reference expressly teaches the combination of an AT1-receptor antagonist in combination with an HMG-CoA reductase inhibitor (p.1, l.27-29), wherein the AT1-receptor antagonist is selected from telmisartan (p.3, l.22) and the HMG-CoA reductase inhibitor is selected from simvastatin (p.5, l.9-11). De Gasparo et al. clearly contemplates embodiments of the invention wherein the combination of at least two therapeutic components comprises an AT1-receptor antagonist (of which telmisartan is expressly disclosed) or a pharmaceutically acceptable salt thereof, and an HMG-CoA reductase inhibitor (of which simvastatin is expressly disclosed) or a pharmaceutically acceptable salt thereof. Please reference p.1, p.3, l.22, and p.5, l.9-11 of De Gasparo et al. This teaching is clear, exact and unequivocally speaks to the contrary of Applicant's traversal that the reference fails to disclose the claimed combination.

Applicant appears to be of the persuasion that the lack of a specific example of the disclosed

combination of telmisartan and simvastatin somehow constitutes a complete lack of teaching of the claimed combination and/or constitutes a teaching away from the claimed combination in view of the fact that other combinations of agents are exemplified. This is not persuasive. A preferred or exemplified embodiment (in this case, compositions using valsartan) does not constitute a teaching away from other embodiments disclosed within the four corners of the reference, including non-preferred embodiments. Applicant is reminded that the disclosure of a reference must be considered as expansively as is reasonably possible to determine the full scope of the disclosure and, as a result, is most certainly not limited to that which is preferred and/or exemplified. Please see MPEP at §2123, which states, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments…Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments." Thus, the fact that other compounds may be exemplified or preferred does not negate or direct the artisan away from the broader teaching of the reference, which expressly provides for, and, thus, clearly contemplates the use of, a combination of an AT1-receptor antagonist (i.e., telmisartan) with an HMG-CoA reductase inhibitor (i.e., simvastatin). Moreover, Applicant is reminded that there is no legal requirement that a reference *must exemplify* a particular embodiment in order to constitute a teaching of the same. A reference will constitute a teaching so long as the disclosure clearly describes and enables such an embodiment and, in the present case, such description is clearly found in De Gasparo et al.

Applicant's additional attempt to patentably distinguish the claimed invention over that of the prior art by asserting that neither the primary nor the secondary references teach or suggest that telmisartan increases the expression of genes regulated by the PPAR-gamma receptor is, as before, not persuasive. The fact that Applicant has recognized another advantage of the combination of telmisartan and simvastatin, when the prior art already acknowledges the desirability of this same combination for the identical therapeutic objectives as presently claimed, cannot be the basis for patentability. Please see *Ex*

parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The explanation of an effect obtained when using a compound cannot confer novelty on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In the instant case, even if De Gasparo et al., did not recognize the advantageous effect on increasing expression of genes regulated by PPAR-gamma when telmisartan and simvastatin were combined, the fact that Applicant has recognized this advantage is not considered a new therapeutic application because the known treatment of the same diseases as presently claimed using this combination of active agents was already known and recognized in the prior art. Though mechanisms of action of chemical entities are no doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C. 103 is based upon the therapeutic applications and effects of the compounds, not the mechanism by which they exert such a therapeutic effect.

Applicant again states that "none of Robl et al., Cecil's Textbook of Medicine, Harlan et al., or Bohm et al. provide what De Gasparo et al. lacks in providing to one of skill in the art as a motivation, reasonable expectation of success, or teaching or suggestion of all of the claim limitations of the claimed invention" (p.18, Remarks), which is also, as before, not persuasive. The record clearly indicates that one of ordinary skill in the art would have been motivated to combine the cited references in such a manner to render the presently claimed invention *prima facie* obvious with a reasonable expectation of success in making such a combination, absent factual evidence to the contrary, and Applicant has failed to provide any factual evidence to the contrary. Applicant's attention is directed to p.16-22 of the rejection presented in the previous Office Action dated March 31, 2006 for this reasoning, which will not be repeated herein so as not to burden the record.

Additionally, Applicant is again reminded that rejections made under 35 U.S.C. 103(a) are based upon the combination of references. As a result, focusing solely on the discrete teachings of each of the cited references is tantamount to examining each of them inside of a vacuum and fails to be persuasive in

establishing non-obviousness because it is the *combined* teachings that are the basis for a proper conclusion of obviousness, not each individual reference alone. In other words, it must be remembered that the references are relied upon in combination and are not meant to be considered separately. To properly conclude obviousness of an invention *does not require the claimed invention to be expressly suggested in its entirety by any one single reference under 35 U.S.C. 103(a).* Rather, the test is *what the combined teachings* of the references would have suggested to those of ordinary skill in the art. Please reference *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

For these reasons, and those previously set forth at p.19-23 of the Office Action dated February 22, 2008, rejection of claims 1 and 8-35 remains proper and is **maintained**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 8-35 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 2 and 7-18 of U.S. Patent Application No. 10/757,295, in view of Harlan et al. (U.S. Patent Application Publication No. 2001/0006656; 2001), each already of record, for the reasons of record set forth at p.23-24 of the previous Office Action dated February 22, 2008, of which said reasons are herein incorporated by reference.

Applicant states that he will file a Terminal Disclaimer if (1) the instant claims be found otherwise allowable and (2) the copending claims pose a double patenting issue at that time. Applicant states that, since the scope of the claims may change and moot these rejections, there is no need to address these issues at this time.

Insofar as the instant claims are not presently in condition for allowance due to the issues described *infra*, and further that the instant claims and the copending claims raise an issue under the judicially created doctrine of obviousness-type double patenting for the reasons previously set forth in the Office Action dated February 22, 2008 at p.23-24, the rejection is **maintained**.

Claims 1, 9-13 and 18-35 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-10, 12-15 and 18-25 of U.S. Patent Application No. 10/899,784, already of record, for the reasons of record set forth at p.24 of the previous Office Action dated February 22, 2008, of which said reasons are herein incorporated by reference.

Applicant states that he will file a Terminal Disclaimer if (1) the instant claims be found otherwise allowable and (2) the copending claims pose a double patenting issue at that time. Applicant states that, since the scope of the claims may change and moot these rejections, there is no need to address these issues at this time.

Insofar as the instant claims are not presently in condition for allowance due to the issues described *infra*, and further that the instant claims and the copending claims raise an issue under the judicially created doctrine of obviousness-type double patenting for the reasons previously set forth in the Office Action dated February 22, 2008 at p.24, the rejection is **maintained**.

Claims 1, 8, 14-19 and 21-35 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-21 of U.S. Patent No. 11/300,947 in view of Drug

Facts and Comparisons (1996), each already of record, for the reasons of record set forth at p.24-25 of the previous Office Action dated February 22, 2008, of which said reasons are herein incorporated by reference.

Applicant states that he will file a Terminal Disclaimer if (1) the instant claims be found otherwise allowable and (2) the copending claims pose a double patenting issue at that time. Applicant states that, since the scope of the claims may change and moot these rejections, there is no need to address these issues at this time.

Insofar as the instant claims are not presently in condition for allowance due to the issues described *infra*, and further that the instant claims and the copending claims raise an issue under the judicially created doctrine of obviousness-type double patenting for the reasons previously set forth in the Office Action dated February 22, 2008 at p.24-25, the rejection is **maintained**.

Conclusion

Rejection of claims 1 and 8-35 remains proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

November 19, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614